

***United States Court of Appeals
for the Second Circuit***



**PETITIONER'S
BRIEF**

77-4097 77-4104

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Nos. 77-4097 and 77-4104

PLEASE RETURN TO
RECORDS ROOM

National Nutritional Foods Association et al.,

Petitioners

v.

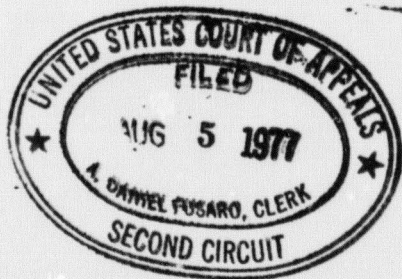
Food and Drug Administration, United States
Department of Health, Education and Welfare, et al.,

Respondents

Petition for Judicial Review of an Order of the
Food and Drug Administration

BRIEF OF PETITIONER MILES H. ROBINSON

Case No. 77-4104



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CITATIONS TO RECORD

FDA Regulations - refers to regulations issued by the Food and Drug Administration on October 19, 1976 (41 Fed. Reg. 46156-46176) and April 19, 1977 (42 Fed. Reg. 20292-20296).

Tr. 2 - For transcript of Rehearing and original hearing

Preh. Tr. - For transcript of prehearing conference of rehearing.

P-2 - For exhibits introduced by the Government, the proponents of the Regulations (e.g. exhibit #2).

O-2-4 - For exhibits introduced by opponents (e.g. exhibit #2 of opponent #4).

WD-4 - For written direct testimonies by opponents (e.g. opponent #4).

Q2 or 2Q - For question (e.g. #2).

A2 or 2A - For answer (e.g. 2).



PRELIMINARY STATEMENT

This is a petition for judicial review, pursuant to the provisions of section 70(f)(1) of the Federal Food, Drug, and Cosmetic Act as Amended, 21 U.S.C. 371(f)(1), and the provisions of Rule 15(a) of the Federal Rules of Appellate Procedure, from an order of the Food and Drug Administration (FDA), which affects, among others, the labeling and composition of vitamin and mineral food supplement products, by amending Title 21 of the Code of Federal Regulations, Parts 80 and 125, now recodified as Part 105 (see Federal Register of April 19, 1977, 42 Fed. Reg. 20292) as published in the Federal Register of October 19, 1976 (41 Fed. Reg. 46156-46176) and April 19, 1977 (42 Fed. Reg. 20292-20296).

REFERENCES TO JURISDICTION, TO PARTIES, AND TO RULINGS

On June 20, 1962, the FDA initiated a proposal to revise the regulations governing dietary foods, notice of which was published in the Federal Register of that date. (27 Fed. Reg. 5815-5818). A hearing was held by the FDA on this proposal pursuant to section 701(e)(3) of the Federal Food, Drug, and Cosmetic Act, as Amended, 21 U.S.C. 371(e)(3), before Mr. David H. Harris, hearing Examiner, between May 7th, 1968, and May 15th, 1970, and identified as "In the Matter of Revising the Regulations for Foods for Special Dietary Uses, 21 CFR 80, 21 CFR 125," Docket No. FDC-78.

On August 2, 1973, in consequence of the aforesaid hearing, FDA revised the regulations by an order (38 Fed. Reg. 20702-20750). Subsequently, 15 petitions for review, consolidated as cases No. 73-2129 et al, were heard by the United States Court of Appeals for the Second Circuit, and judgment rendered on August 15, 1974, (National Nutritional Foods Association v. Food and Drug Administration, 504 F. 2nd 761.

The Court stayed the regulations in their entirety (p. 785); held that all essential nutrients must be allowed in a food supplement, even though FDA after twelve years of proceedings had failed to fix Recommended Daily Allowances (RDA's) for some of them (p. 787); held that potencies of nutrients higher than the RDA are not necessarily drugs (p. 789); held that the FDA hearing Examiner erred in denying to petitioner a cross-examination of Dr. Sebrell, the witness from the Food and Nutrition Board (hereafter "Board") of the National Academy of Sciences, which had formulated the RDA's on which the regulations were based; and remanded the case to the FDA with instructions, among other things, to reopen the record for petitioner to cross examine

"Dr. Sebrell or some other qualified member of the Board, in order to probe into such important matters as how the RDA's were prepared***whether those who prepared them had any biases that might affect their judgment***what doubts they entertained***what inconsistencies there were***whether vigorous cross-examination...would have provided a record that

would have affected the judgment of a reviewing court on the question of sufficiency" (Ibid, 798-9).

FDA on September 30, 1975, announced the reopening of the hearing (40 Fed. Reg. 4485) (hereinafter referred to as "FDA Rehearing"), which was held November 10-14, 17, 1975. The FDA docket No. FDC-78 was redesignated No. 75N-0107, but continued the numbering of exhibits and pagination of the daily transcript as before. The presiding officer was Administrative Law Judge Daniel J. Davidson. The witness was Dr. Alfred E. Harper, Chairman of the Committee responsible for the Board's 1974 RDA's and a member of Dr. Sebrell's Committee that formulated the 1968 RDA's. (Tr. 32453).

In the original FDA hearing of 1968-1970, petitioner was personally opposed to the FDA food supplement regulations, but not having learned of the proceedings until after the deadline for participants had passed, he served in them as nominally the representative of the similarly interested National Health Federation (NHF). Petitioner's interest was subsequently served by the petition of Lutz et al for review in this Court (Case No. 74-1055, consolidated as 73-2129 et al). This Court responded to that petition with a remand instructing FDA to allow petitioner to cross-examine Dr. Sebrell or suitable surrogate, which had been erroneously denied to petitioner in the original FDA hearing. In the subsequent FDA Rehearing petitioner appeared on behalf of himself, as well as of NHF, Lutz et al, and the

Federation of Homemakers. (Tr. 32413).

Petitioner is now appealing as a direct participant in the FDA Rehearing, participation having been opened to anyone by an order of the Commissioner. (40 Fed. Reg. 23245, 44858).

A prehearing conference was held by Judge Davidson on October 31, 1975, during which petitioner concluded that Judge Davidson was unjudicial, prejudiced against petitioner, and had laid down unfair ground rules so that the ensuing rehearing could not be fair. Accordingly, petitioner on November 4 and 8, 1975, filed motions and affidavits in this Court (Case No. 73-2129 et al) to show cause why proceedings should not be stayed pending a hearing on whether Judge Davidson should be disqualified. These motions were withdrawn without prejudice.

During the FDA Rehearing, petitioner and his associate, Dr. Donald R. Davis^{*}, cross-examined Dr. Harper for approximately half of five days, the remaining time being used by cross examiners representing seven other parties.

Administrative Law Judge Davidson on February 20, 1976, upheld the RDA's and the regulations in every particular. The FDA Commissioner, in his final orders of October 19, 1976, (41 Fed. Reg. 46156-46176) and April 19, 1977 (42 Fed. Reg. 20292-20296) also

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rejected the challenge to the RDA's, but made some minor changes in the regulations (hereinafter "FDA Regulations").

Meanwhile, Congress had taken a hand in this matter and enacted new legislation (Pub. L. 94-278, Title V, April 22, 1976), which restricts FDA's authority to limit both the maximum potency of vitamins and minerals and also the inclusion of ingredients in dietary supplements.

Petitioner on May 16, 1977, filed a petition for review of the FDA Regulations in this Court. At that point he acted solely pro se, because it was not possible to raise the substantial attorney's fee for legal counsel, and only an attorney may represent persons other than himself in court.

Petitioner's case was docketed in this Court as No. 77-4104, and later consolidated with another petition for review, No. 77-4097, filed by the National Nutritional Foods Association et al.

Petitioner is adversely affected by the FDA Regulations, and alleges that this case has not been previously before this Court except as described above.

ISSUES PRESENTED

This petition for review involves eight issues.

Issue No. 1: Whether Dr. Harper and the Board were biased in favor of the food industry, so as to affect the levels at which they set the RDA's.

Issue No. 2: Whether nutritional requirements and the RDA's derived therefrom should be based on the criterion of optimum nutrition rather than "adequate" nutrition.

Issue No. 3: Whether the RDA's were unscientifically set low in order to fit the current food supply.

Issue No. 4: Whether the refusal of the Administrative Law Judge to allow further cross-examination and rebuttal witnesses on the statistical methods used by the Board was reversible error.

Issue No. 5: Whether the refusal of the Administrative Law Judge to allow further cross-examination and rebuttal witnesses regarding use, in the formulation of RDA's, of animal requirements established by the National Academy of Sciences was reversible error.

Issue No. 6: Whether the evidence was sufficient to support certain RDA's, aside from issues of statistical methodology and consideration of the Academy's animal requirements.

Issue No. 7: Whether certain inequitable and improper rulings of the Administrative Law Judge during the course of the FDA Rehearing and prehearing conference constituted reversible error.

Issue No. 8: Whether the relief prayed for is appropriate to this petition for review.

EXPLANATORY STATEMENT RELATING
TO ALL ISSUES

Petitioner is a medical doctor, specializing in nutrition,

who has taught and published original research while in the departments of pharmacology and physiology at Vanderbilt Medical School and in the department of pharmacology at the University of Pennsylvania Medical School. He has never had any commercial interest in the disputed regulations, and throughout the proceedings has been motivated solely by the belief that the health of countless consumers would be adversely affected by the regulations, first by impairing their ability to remedy the deficiencies of modern food with food supplements; and second, by lulling them into a false sense of nutritional security founded on faith in RDA's which he believes have been unscientifically set too low by the regulations.

This Court has emphasized that the FDA grounded the regulations on the necessity to promote honesty, fair dealing and full information to consumers regarding foods, (504 F. 2d 768). None of these aims will be achieved if the RDA's, "the scientific validity" of which was "a question of central importance to the agency's promulgation of the regulations" (Ibid., 793), are substantially inaccurate and misleading.

This Court's decision in 1974, and the new federal law in 1976, have together had the effect of broadening and enlarging FDA's nutritional concepts, and expanding the consumer's freedom of choice in dietary supplements. There remains, however, the question of whether the RDA's have been objectively and scientifically determined;

or whether, in order to protect the reputation of the food industry for supplying nutritious food in the market place, the RDA's have been set below what would achieve optimum health for Americans. The wide application of this question is evident

It so happens that the FDA regulations at issue are the sole determinant of these RDA's. They have become the standard by which the consumer is expected to, and for the most part undoubtedly will, judge the nutritional adequacy of everything he eats.

Petitioner is in favor of labelling food and food supplements with their nutritional content in terms of the RDA's supplied, but is opposed to the use of the proposed RDA's, because they have not been carefully and scientifically determined by impartial and competent authorities according to the criterion of optimum health.

STATEMENT OF THE CASE ON ISSUE OF
BIAS OF DR. HARPER AND THE BOARD

In its remand, this Court stipulated that the witness should be Dr. Sebrell or some other qualified member of the Board (504 F. 2d. 799). FDA counsel stated that Dr. Sebrell did not appear because of anticipated stress and strain of the cross examination, unfamiliarity with post 1968 development of RDA's, and conflict of interest inherent

* Incorporation of the RDA's into food labelling generally may be seen in FDA's new food labelling regulations. (38 Fed. Reg. 2124-2164; 6950-6975; 20702-20750. 39 Fed. Reg. 20878-20908. 42 Fed. Reg. 14312-14, 14328-34, 14498).

in his employment in the food industry. (Government's Response to Prehearing Conference Request For Information dated November 6, 1975).

Dr. Harper was a member of the Board's 1968 RDA Committee and its chairman in 1974. (Tr. 32453-54). His financial connections with the food industry have been substantial throughout his professional career. His first advanced degree was obtained with the assistance of a scholarship from the Maple Milling Co. in 1945. Subsequently, he received an honorary award from the Borden Co. (Tr. 32531), and received research support from the National Livestock and Meat Board. (Tr. 32530). He has been on the Scientific Advisory Committee of the American Institute of Baking. (Tr. 32558). The Nutrition Foundation gets its funds from the food industry (Tr. 32530), and Dr. Harper has received research support from this Foundation (Tr. 32530), which one year amounted to \$10,000. (Tr. 32536). He has been a member of the Scientific Advisory Committee of the Nutrition Foundation which reviews the Foundation's grants for research. (Tr. 32535). The Foundation publishes the journal, Nutrition Reviews (Tr. 32532). From 1956 to 1961, he was associate editor of Nutrition Reviews, and contributed anonymous articles to it for which he was paid. (Tr. 32798).

Dr. Harper is a regular consultant to various food and drug companies: General Mills, Pillsbury, Proctor & Gamble, and

Chattem Drug Co. for a total of \$1,000-\$1,500 per year (Tr. 32498, 32500, 32557, 32558, 32637). He has been a consultant to the Searle Drug Co. for the last 3-1/2 years, at \$10,000 per year, which is 20% of his income. (Tr. 32506, 32500). The significance of this connection is that Searle employs him for his expertise on amino acids; one of which, aspartic acid, is a major ingredient of the artificial sweetener, Aspartame (Tr. 32502), made by Searle.

When Dr. Harper was asked it was not a fact that General Foods had put up \$15 million to build an Aspartame plant for Searle, he denied knowledge of the "financial details", but testified:

"I know that they [General Foods] are planning to use Aspartame and that they have been involved in some way. . . ." (Tr. 32517).

Dr. Harper placed Aspartame and Searle in a category separate from food and the food industry, but contradicted himself:

"I accepted that consultantship because I felt it posed no conflict of interest for me because that company does not produce vitamins or minerals or food stuffs. I have consulted occasionally for companies, such as Proctor and Gamble, Pillsbury, McGaw Laboratories." (Tr. 32498, see also 32500).

Regarding Aspartame, Dr. Harper said "it would be very appropriate to use it in foods generally, and. . . in special dietary foods" (Tr. 32511). He said the substance was not a drug, but neither was it a food. When pressed on this question, he said even sugar was not a food. (Tr. 32512-13). He admitted that Aspartame

is "composed of two amino acids which are nutrients" (Tr. 32504), but that it is "not used as a nutrient, it is used as a flavoring substance." (Tr. 32502).

In connection with current charges by the FDA that Searle had falsified various research data submitted to FDA, Dr. Harper was asked whether any of his research for Searle was involved in these charges. (Tr. 32559). Judge Davidson sustained an objection; and as he so often did at crucial junctures contrived "a little break in the action right here" (Tr. 32559), went off the record, introduced several extraneous matters, diverted petitioner from his offer of proof, ended in an assertion that he either "made a mistake or did not think that there was much reason for you Dr. Robinson to reply" (Tr. 32560), and characterized the time spent on Aspartame as close to having been "wasted". (Tr. 32562). Petitioner made his offer of proof (Tr. 32561), pointed out that the subject bore strongly on the qualifications of Dr. Harper as a scientist, but Judge Davidson ruled against the question. (Tr. 32562).

Dr. Harper directly and indirectly has benefited from substantial funds from General Foods. He was the first professor under a grant of \$14,000-\$18,000 per year from the General Foods at MIT in Boston which lasted four years. (Tr. 32523, 32525). In the spring of 1975 (Tr. 32526), after Dr. Harper was asked by Dr. Forbes of FDA in the first months of 1975 to testify at the FDA Rehearing (Tr.

32457), General Foods moved the funds for this professorship, in the amount of \$50,000 per year, to Dr. Harper's department at the University of Wisconsin for the benefit of Dr. W. G. Hoekstra, a long-time associate of Dr. Harper's. (Tr. 32525-7). At the time of the FDA Rehearing, the professorship was still in abeyance, in that Dr. Hoekstra had not yet been formally appointed. (Tr. 32527). Dr. Harper admitted that he may have discussed the RDA's with General Foods. (Tr. 32518).

Dr. Harper was uncertain whether other members of his RDA committee were receiving grants or consultation fees from food and drug companies. (Tr. 32589). It was determined that Dr. Robert O. Nesheim, an employee of the Quaker Oats Co., was a member of the Board with Harper. (Tr. 32593), and that E. M. Foster, the Director of the Food Research Institute of Wisconsin, which receives funds from the food industry, was also a member of the Board. (Tr. 32593-4). One of the chief sources of funds for the Board has been the Nutrition Foundation, which is supported and controlled by the blue ribbon food corporations of the U. S. (Tr. 3414).

Dr. Harper helped organize a group called the Nutrition Consortium (Tr. 32827), which is financially supported by the Nutrition Foundation, in turn controlled by the food industry. (Tr. 32530). The Consortium opposes those who advocate large doses of vitamins, for example, in the treatment of schizophrenia. (Tr. 32828, 32829). In March 1973,

Dr. Harper wrote a letter, published in Nutrition Notes, a journal published by the American Institute of Nutrition (Tr. 32801), on the Executive Committee of which he has served. (Tr. 32802). This letter advocated "guerilla action rather than saturation bombing" of Adelle Davis and others who advocate the use of large doses of vitamins. (Tr. 32802).

• "Although large-scale counter-campaigns are unlikely because of their cost and unproven effectiveness, being prepared to make a few thrusts in the right place at the right time with appropriate armament (guerilla action rather than saturation bombing) is preferable to an attitude of futility, and who knows it might eventually reverse the tide more effectively than a head-on onslaught." (Tr. 32804).

The day after Senator Proxmire made a speech on June 10, 1974, sponsoring the bill which was later to restrict FDA's control of dietary supplements (see 41 Fed. Reg. 46156), Dr. Harper sent the senator a telegram which was not only emotional but factually incorrect. Motion to admit the speech (0-957) and the telegram (0-956) into evidence was denied (Tr. 33521).

In his telegram, Dr. Harper called the speech "obviously a mixture of half-truth, un-truth and outright falsehoods." But under cross-examination, the only alleged error Dr. Harper could find was that the table of various RDA's (0-957, p. 510177), showed that, in Harper's opinion, all the RDA's therein "appear without distinction as five editions of the recommended dietary allowances" (Tr. 32815-6). But even this remaining allegation was false, as may be seen in

exhibit 0-957.

The truth is that each set of RDA's in the Table is clearly labelled by headings and footnotes as to its source.

When pressed under cross examination Dr. Harper finally admitted that both at the time he sent the telegram and now, he understood all this (Tr. 32821), and did not question the accuracy of any part of the Table (Tr. 32822). He admitted that he had sent the telegram when he was in an "emotional" and "very angry" state of mind. (Tr. 32815). *

ARGUMENT ON ISSUE OF BIAS OF DR. HARPER AND THE BOARD

This Court, in its remand instructions, recognized the relevance and materiality of any bias which the Board and Dr. Harper may have had which would affect their scientific judgments. (504 F. 2d 798).

The most important qualification of a nutritional scientist, after basic competence in his field, is an open mind, alert and genuinely interested in every clue that might lead to an improvement in mental and physical strength. The most certain way to close that mind is to surround it with conflict of interest.

Throughout the FDA hearings on special dietary foods, petitioner has emphasized that the food industry, and especially the food processors, benefit financially by having the RDA's set as low as possible. Their public image as the purveyors of nutritionally ade-

* Further light on Dr. Harper's emotional state was provided by his home-town newspaper, in which he described his cross examination as "one of the most horrendous experiences of my life." (The Capital Times, Madison, Wis., November 27, 1975).

quate food is enhanced, and they need spend less money ensuring that perishable vitamins and evanescent trace minerals are incorporated in food during the growing process and remain there in the course of harvesting, transportation, storage and processing.

It is, therefore, important to know whether the Board and especially its chairmen, are beholden to the food industry for money or other favors since that would tend to warp their scientific judgment with respect to healthful levels of the RDA's. ^{*} Instead of concentrating solely on what levels would produce optimum mental and physical vigor in 210 million Americans, and letting the chips fall where they may, the Board would be under powerful pressure to set the RDA's lower than would be scientifically sound. Such conflict of interest would explain why the Board used, as will be described, a lower criterion than optimum health, correspondingly lower RDA's, incompetent statistical methodology, and nutritional data from animals which omitted crucial information compiled by its parent body, the National Academy of Sciences.

The Board purports to be very scientific, but even its definition of the RDA's is confused. (P-1165, p. 3). The first paragraph of the definition begins with the sentence, "RDA are recommendations for the amounts of nutrients that should be consumed daily." This sounds as if an individual should take a dose the size of the RDA's in order to satisfy his requirement. But the first sentence in the next

* The more that Board members are cross examined, the more conflict of interest turns up. See Coffman Exceptions, case Nos. 73-2129 et al, pp. 40-42, 166-168.

paragraph of the definition states that "RDA should not be confused with requirements." Eventually, the reader may discover, as he reads through statistical allusions here and there in the Board's 1974 report that the first sentence means that if everyone in the whole population took the RDA, the dose is high enough to cover the differing requirements of about 97.5% of that population. Whereas the other sentence refers to the true requirements of individuals.

Another example of the obfuscation which has been engendered by this elite is the perplexing difference in nomenclature between the RDA's of the Board and those of the FDA. The middle initial of the Board's RDA's stands for "Dietary", whereas in the FDA's U.S. RDA's it stands for "Daily". (See Fed. Reg., October 19, 1976, p. 46172). This has caused much confusion for almost everyone trying to understand the subject. Over five pages of cross-examination of Dr. Harper were required to bring out that there was no scientific reason for the difference, at the end of which time he said the nomenclature was adopted in an unsuccessful effort to avoid confusion. (Tr. 32604-8). Dr. Harper testified that his professional colleagues were not well versed in RDA's and misinterpreted them (Tr. 32703).

Dr. Harper's financial favors from General Foods have been unusually large; and his ties to the food industry, especially through the Searle-Aspartame connection, placed General Foods and other food processors in a position to exert considerable influence on Dr. Harper to get the kind of RDA's most congenial to their business op-

erations. That the food industry wanted the RDA's exactly as they now stand is proved by the fact that throughout the long FDA hearing of 1968-1970 and the FDA Rehearing of 1975, the food industry made no effort to change the RDA's.

The timing of the transfer of the General Foods professorship from MIT where it had been for ten years since 1965 (Tr. 32525) to Dr. Harper's department at Wisconsin in early 1975 (Tr. 32526), and the holding in abeyance of Dr. Hoekstra's appointment as late as November 1975 (Tr. 32527) when Dr. Harper was cross-examined, suggest that the professorship may have been a reward for Dr. Harper's agreeing to testify (a "horrendous experience"), and contingent on his performance as a witness at the FDA Rehearing.

The lengths to which Dr. Harper went to put an artificial distance between himself and General Foods in connection with Aspartame, even denying that sugar is a food (Tr. 32512-13), shows how concerned he was to minimize any connection between his obligations to General Foods and the RDA's which he thinks he may have discussed with them.

He expressed a concern for conflict of interest regarding consulting for food companies, but this seems to have been a pretense since he immediately repudiated that concern by revealing he had consulted for them. (Tr. 32498).

With regard to Dr. Harper's ill-founded attack on Senator Proxmire, the relevance, materiality and credibility of the Senator's speech and Dr. Harper's telegram were sufficiently established by

the witness, and it was prejudicial error on the part of Judge Davidson to deny their admission into evidence.

In summary of Dr. Harper's bias, here is a chairman of the committee of the Board charged with formulating the RDA's, who in his opposition to the proponents of dietary supplements thinks in terms of guerilla warfare and saturation bombing. Who, in an angry and emotional state, sends a slanderous and knowingly untruthful telegram to the U. S. Senator sponsoring the bill which removed unwarranted restrictions on dietary supplements. Who was obliged under cross examination to retract the false and intemperate charges in that telegram.

This is not the behavior of a scholarly, fair-minded scientist, who should be occupying the Olympian position of Chairman of the Committee which sets the nutrient needs for the health of 210 million Americans.

On the contrary it is the behavior one would expect from a man obsessed with loyalty to a group, not to scientific principles, swimming out of his depth in the deep waters of conflict of interest. Quite clearly the people to whom Dr. Harper pays first allegiance are high officials in the food industry. After all, it is they who have been paying him.

STATEMENT OF THE CASE ON ISSUE OF OPTIMUM
NUTRITION v. "ADEQUATE" NUTRITION

This Court in its earlier decision on the regulations has used, and recognized the validity of, the term "optimal" in connection with nutrition of an individual. (504 F. 2d. 784, 791-2).

Dr. Harper testified that there was no criterion for optimum nutrition, and that "The term that should be used is adequate nutrition." (Tr. 32716). This deprecation of "optimum," however, is not supported by the Board's own reports, which in general describe the ongoing discoveries of nutritional science which purportedly result in periodic adjustments of the RDA's reflecting ever more subtle signs and symptoms of malnutrition. For example (all emphasis supplied):

"Although the minimal requirement of vitamin B₁₂ for clinical remission of deficiency states appear reasonably established, further studies are needed to establish the optimal requirements for health." (P-651, p. 49).

". . . 10 mg of ascorbic acid. . . may not be satisfactory for the maintenance of optimal health. . ." (P-1165, p. 64).

". . . optimal responses are obtained with a daily parental dose of 1 mg (of vitamin B₁₂)" (Ibid., p. 78).

Dr. Harper considers a person healthy if he has no obvious problems (Tr. 32976), only suffers a major illness every few years (Tr. 32585), and is not visibly stunted (Tr. 32986-88). He stated, in effect, that the American population is protected by an ability to adapt to unacceptably low doses of nutrients (Tr. 33033-34), and that ordinary foods today must be satisfactory since man has survived on them for several billion years. (Tr. 32618-9). He believes that one-third (20 mg) of FDA's proposed U.S. RDA for vitamin C (60 mg) would maintain health. (Tr. 32978).

ARGUMENT ON ISSUE OF OPTIMUM
v. "ADEQUATE" NUTRITION

The levels of the RDA's obviously depend upon the degree of health they are intended to achieve. If, for example, one were satisfied with a slightly scorbutic sailor a century ago who could still pull on a rope, one could set his nutrient requirement for vitamin C far below the optimum amount. Dr. Harper dwelt at length on ancient scurvy of this sort. (Tr. 32972-73).

The Board's reports express an interest in optimum nutrition.* But when one goes behind the scenes in cross examination of its Chairman, Dr. Harper, one discovers that in actuality he favors criteria which lead to mediocre nutrition. Dr. Harper's endorsement of an RDA for vitamin C one-third FDA's proposed U. S. RDA is enough by itself to raise grave doubts about the Board's scientific competence.

Top level scientists such as Dr. Arnold F. Schaefer, former director of the National Nutrition Survey conducted by the U. S. Department of Health, Education and Welfare (WD-G-Schaefer, Appendix A, curriculum vitae), in contrast to Dr. Harper use and depend upon the concept of optimum nutrition. (Tr. 17474).

* Dr. Sebrell has stated that there were wide differences of opinions as to the optimum intake of nutrients, but Dr. Harper disagreed (Tr. 32719-22). It is thus understandable why Dr. Sebrell chose not to undergo cross examination on the RDA's, and why Dr. Harper and other FDA witnesses (Tr. 1451, Filer; 14566, Herbert; 8620 Schweigert) have vigorously rejected the troubling concept of optimum nutrition. It would not be easy to ride both sides of this fence under cross examination.

STATEMENT OF THE CASE ON ISSUE
OF SETTING RDA's TO FIT THE FOOD SUPPLY

The record contains considerable evidence that the Board has been constantly looking over its shoulder at the nutrient supply in the marketplace, and has thereby been influenced to set the RDA's so as not to exceed the quantity which would be available to the consuming public.

For example, in the case of vitamin E, the Board frankly admits that its "allowances are based primarily on the d-a-tocopherol contents of diets." (P-1165, p. 57). Furthermore, when the Board discovered that the total amount of vitamin E available in American food was less than it believed in previous years, the Board by its own admission cut the RDA approximately in half (Ibid., p. 59). Dr. Harper agreed that there were new sensitive criteria for detecting vitamin E deficiency which the Board did not use. (Tr. 33362-63, 33397).

For infants, the allowances of vitamins E, C. and thiamin are all largely based on what is found in mother's milk (P-1165, pp. 60, 64, 67). But it is well known that since man cannot synthesize these vitamins, the content of such milk is totally dependent on how much of these vitamins the mother eats, and wide variation of the vitamin content of such milk is well established (Tr. 13125, 3288). It is simply assumed that what the breast fed infant gets is what it needs.

In the case of vitamin B₁₂ for infants, the Board states that since "overt vitamin B₁₂ deficiency does not occur in infants breast-

fed by women with adequate serum B₁₂ levels" (emphasis added), the RDA for infants is set at the level found in their milk (P-1165, p. 79). Again, since the subject seems to be healthy, what it gets is assumed to be what it needs.

After the FDA Rehearing was terminated, there happened to be published a government article entitled, "Nutrition in the United States: 1900 to 1974", by Willis A. Gortner of the U. S. Department of Agriculture. Petitioner on March 30, 1976, filed a motion and memorandum, together with the article, for admission into the FDA record, and the FDA Commissioner admitted it into evidence on April 19, 1977. (42 Fed. Reg. 20293). *

The Gortner article is fully described in the aforesaid petitioner's memorandum. In summary, it provides the per capita availability, with some exceptions, of 4 minerals and 7 vitamins over the last 74 years. The article was published in the journal, Cancer Research, and appears from its context to have been produced as a defence against the theory that the rise of cancer incidence might be due to a decrease of available nutrients.

* The Commissioner, in admitting the article, alleged that it should have been introduced at the FDA Rehearing. While the article appeared in the November 1975 issue of Cancer Research and the Rehearing was held from November 10 to 14, 17, the National Medical Library has advised petitioner that its records show that the issue containing this article was received on December 9, 1975.

Table 3 of the article lists the availability for consumption per capita per day of various nutrients. For the latest year shown, 1974, figures are given which, if one sets them against the U. S. RDA's, show an availability of the following percentages of the U. S. RDA's: vitamin A 164%, C 198%, B₁ 129%, B₂ 137%, niacin 117%, B₆ 114%, B₁₂ 162%, calcium 95%, iron 102%, phosphorus 154%, magnesium 87%.

A footnote to the table states that this availability includes use for pet food, and does not allow for waste in the home nor loss of nutrients during processing or cooking, so the above percentages actually available for human consumption must be substantially less. The Board's 1974 text confirms that the amounts of nutrients needed per capita in the food supply should be larger than the RDA, because of losses in processing and preparation of food. (P-1165, p. 3).

ARGUMENT ON ISSUE OF SETTING RDA'S TO FIT THE FOOD SUPPLY

What we have here in this issue is another tile in the mosaic of evidence, no single piece of which may be sufficient to convict the Board and its adherents of inadequate self-serving RDA's; but each of which adds to the picture, brings out the design, and strengthens the case.

First, there is the powerful troika of commercial interests: the food, drug and medical industries, each of which benefits greatly from food of low nutrient density. The food industry has high profits from "junk" food which is cheap to produce. The drug, medical and

surgical enterprises thrive on the diseases of malnutrition. All of them have an interest, whether consciously selfish or not, in preserving, with the help of their allies in the FDA, the reputation of the "American food supply. . . unsurpassed throughout the world in both quantity and nutritional value." (0-76-58, FDA's campaign Against Nutritional Quackery, GPO No. 0-721-439). The new RDA labels on most packaged food today endorse this reputation; and the lower the RDA's are set, the automatically stronger is the endorsement.

Second, there has been the sustained and wholly reprehensible effort by the troika and a subservient FDA, throughout FDA's great hearing of 1968-70, to pretend that there was no significant malnutrition in the country (See 31 Fed. Reg. 15734 re sec. 125.2 (b)(3)), in the hope of relegating dietary supplements to the category of placebos. *

Third, there has been the airy and unnecessary rejection of the criterion of optimum nutrition, which makes possible undesirably low RDA's.

Dr. Harper and the Board take comfort in the theory that the body can adapt to unacceptably low levels of nutrients, and in the belief that modern food is as good as ancient unprocessed food. The Board in setting the RDA's often proceeds on the bootstrap theory that the

* When, after great effort, petitioner finally overcame FDA's strenuous objections to allowing Dr. Schaefer to describe the "alarming" evidence of American malnutrition revealed by HEW's National Nutrition Survey of which he was the Director (See p. 20 herein), FDA counsel Anderson threw in the sponge with the remark, "There you go." (Tr. 17780).

amount of nutrients we get is what we need. To hold these views today is to be either a thoughtless Pollyanna, or one with ulterior motives, not an alert and competent scientist.

The Gortner report reveals a remarkable coincidence. The RDA's, which are recommended daily allowances per capita, turn out to be quite close to the per capita supply of the respective nutrients. *

As stated in petitioner's memorandum for admission into evidence, he learned of the Gortner article from an official of the Grocery Manufacturers of America. In any event, it may be safely assumed that the Board, with its close ties to the food industry, has been well aware of government food consumption data reaching back to the year, 1900.

These data show that the margin between the RDA levels and their availability in the food supply is relatively narrow. In the case of calcium and magnesium there is actually not enough of these nutrients even at present levels of the RDA's, and some of the other margins are very close. Furthermore, if the human RDA's were raised to fit the nutritional requirements of rats or monkeys as determined by the National Academy of Sciences (See issue No. 5), the margins would be little changed for vitamins B₁, B₂, B₁₂ and biotin (showing, incidentally, the justification for such extrapolation);

* The Hearing Examiner's Report of January 25, 1971, found that the U. S. food supply probably did not contain enough iron, and that there was not an abundant amount of vitamins A, C, B₆, and E, and of the mineral calcium. (Report pp. 46, 70).

but the supply of other nutrients would not meet such an elevated RDA, in most cases failing by many fold. The Gortner data lacks figures for six essential nutrients for which there are RDA's, which is unfortunate, but this simply highlights the inadequacy of interest in nutrition on the part of the U. S. Department of Agriculture.

Note that the Board's action of 1974 in substantially reducing many of its RDA's as compared to its 1968 levels (Tr. 32677^{*}) automatically produces an improvement on paper in the nutritive adequacy of the American food supply.

The Gortner data reinforce our argument made earlier that there is bound to be great pressure on the Board from the food industry to hold the RDA's below or near the food supply where most of them now are. For it is reasonable to believe that if the RDA's substantially exceeded their availability in the market place, and this became generally known, there would be considerable public dissatisfaction and pressure to do something about the highly profitable "junk" food which now seriously dilutes the nutrient density of the food supply.

STATEMENT OF THE CASE ON ISSUE OF STATISTICAL METHODOLOGY

The Board's 1974 text states that "It is only within the framework of statistical probability that RDA can be used legitimately"

* See also reply brief of Lutz et al., Case No. 73-2129 et al. in this Court, Table I, pp. 1a-2a.

(P-1165, p. 14). Dr. Harper testified that it is standard procedure for the Board to depend upon statistical principles "Insofar as is possible" in the formulation of the RDA's. (Tr. 32766).

Dr. Harper stated that in setting the RDA's, the statistical principles of probability and standard errors were used for the RDA's of protein, vitamin C, thiamin (B₁), iron, and to some degree for other nutrients (Tr. 32608, 32610-32611); and that the Board would have liked to have used them for the RDA's of all 17 nutrients. (Tr. 33037).

The statistical methodology itself (Tr. 32969-70) is not complicated. First, the average nutrient requirement is determined from various sources, such as balance studies and experimental depletion and repletion studies. (P-1165, pp. 7-8). This average figure as determined on man tends to be crude, as the Board explained:

" . . . even under the best conditions, only a small number of subjects can be studied in a single experiment. . . For some nutrients. . . there are so few experiments on human subjects that requirements must be estimated either from information about the requirements of other mammals or from information about the minimum amount of the nutrient known, from food analyses and dietary surveys, to be consumed by apparently healthy people. " (P-1165, p. 5, emphases supplied).

Second, since approximately half of a population will have requirements greater than the average, the Board, in order to esti-

mate an RDA which is adequate for "nearly all" persons, requires information about the frequency and magnitude of deviations from the average. This statistical information is scarce, and the Board resorted to two simplifying assumptions. One of them approximates the frequency distributions with the Gaussian mathematical form ("normal" bell-shaped curve)* (Tr. 33031-37), in which case about 97.5% of the population would have its needs met by an RDA set equal to the average requirement plus two "standard deviations." (P-1165, pp. 8, 16, 40-41; Tr. 32970). The second assumption was that standard deviations for nutrient requirements are about 15% of the average requirement, or in other words that the "coefficients of variation" are 15%. (Tr. 32612, 32613, 32764).

For example, with these assumptions, if the average requirement for a nutrient were 10 mg, the standard deviation would be 15% of 10 mg = 1.5 mg, and the RDA would be set at $10 + 1.5 = 13$ mg. This would be large enough to meet the needs of 97.5% of the population.

Cross examination of Dr. Harper revealed that the two above mentioned assumptions made by Dr. Harper and the Board are scarcely documented and highly questionable. Both of them, and a

* For the curves used as a tool in questioning of Dr. Harper on the statistical aspects of the RDA's, see exhibit 0-932 A through D.

third to be mentioned, have the effect, as will be described, of significantly lowering the RDA's.

As stated above, the Board arbitrarily assumed a coefficient of variation of 15% for all nutrients. Dr. Harper admitted that the coefficient for this kind of application may range from 10% to 30% or more (Tr. 32768, ^{(32769, 33131),} and that the small number of subjects used in experiments to determine the average nutritional requirement may make it impossible to know what figure in this range would be appropriate. ^{(66).} (Tr. 32765-) Notably, the Board in its 1968 formulation of the RDA for vitamin C used a coefficient of 38%. (Tr. 33136, P-1165, p. 32).

Dr. Harper testified that except possibly for the protein requirement, we really do not know what the shape of the distribution curve is out in the crucial region of two standard deviations above the mean. (Tr. 33041). There is one reference, to Beaton, in the 1974 RDA text which discusses distribution curves, but Dr. Harper is not sure whether it shows that the nutrient requirements are actually Gaussian. (Tr. 33040).

Dr. Harper testified that there are biological phenomena for which the Gaussian distribution does not fit very well at all, in fact very poorly, and this is called skewness. (Tr. 33038). He agreed

is the intake relative to average "need" measured in units of one or more standard deviations (σ).

It will be seen that using the Board's criterion of 2 standard deviations, this point on the Gaussian curve corresponds to about 2.5% of the population not having their needs met, or about 97.5% having their needs met.

But if the non-Gaussian curve II is used to obtain the same approximately 2.5% unmet needs, then one must add about two and a half standard deviations to the average requirement in order to set the RDA. More serious skewing of the curve, of course, could further raise the RDA dose. The full consequences of skewing, however,

that the Board's RDA texts do not cite evidence that the distribution is Gaussian for any nutrient. (Tr. 33038).

Of great significance, he testified that if the distribution were non-Gaussian, the range of people not covered would be exceedingly wide and important. (Tr. 33052, 33059). This phenomenon can be seen graphically on Dr. Davis' charts in exhibit 0-932 A and B, the applicability of which Dr. Harper did not question.

In exhibit 0-932A, curve I is Gaussian, and curve II is a possible non-Gaussian curve. In exhibit 0-932B, the incidence of nutrient needs not met for these two curves is on the ordinate, expressed on the left as a percent and on the right as numbers of people in the U. S. population of approximately 200 million. — On the abscissa

Most of the statistical part of the cross examination of Dr. Harper, insofar as it was allowed, was conducted by petitioner's associate, Dr. Donald R. Davis, with great competence and temperance, as an examination of the transcript will show. (Tr. 33029-33138). Since this was a fact-finding hearing there was every reason why the examination, involving two experienced scientists, should have been controlled by the Presiding Officer in an easy and

* The Board states that "RDA have been established for only about one-third of the essential nutrients" (P-1165, p. 19); that is, for 17. (Ibid., fold-out page). So the total number of essential nutrients is around 51.

become clear only in the context of a third assumption made by the Board.

This third assumption was to ignore the fact that the requirements for forty or more essential nutrients* must be met simultaneously in each person.

Dr. Harper confirmed that the Board did not consider the statistical problem involved in meeting the needs for more than one nutrient in a person. (Tr. 33086-7). He agreed that as an individual's needs for more than one nutrient are considered, even assuming a Gaussian distribution, the percentage of the population whose nutrient needs are not met goes up, and that this is important. (Tr. 33084-97).

and constructive way. But Judge Davidson did not do this, and thereby failed to follow the mandate of this Court.

Judge Davidson took full advantage of Dr. Davis' unfamiliarity with a cross-examiner's right⁵ repeatedly to harass Dr. Davis, throw him off balance, and raise trivial points of technique. Judge Davidson inaccurately charged arguing (Tr. 33031), 33032), improper comment (Tr. 33034), failure to pay attention (Tr. 33035, 33036), arguing (Tr. 33042), loaded question (Tr. 33043, 33044), and described himself as a "sucker" for permitting further questioning. (Tr. 33051).

At a point when Dr. Davis had established with Dr. Harper that a non-Gaussian curve throws off the 97-1/2 percent meeting of

needs by "an exceedingly wide range" (Tr. 33052), and then asked the witness for actual numbers, Judge Davidson said the inquiry "is silly", and stopped the line of questioning. (Tr. 33053).

Not only was this a clearly erroneous ruling in view of the fact that numbers are the essence of statistics in general and the problem at hand in particular (the whole logical course of the line Dr. Davis was pursuing was clearly evident on the 3 x 4 foot blow-up pictures of exhibit 0-932 displayed in the hearing room), but Judge Davidson increased the harassment first with the words, "Proceed, sir, with another question" (Tr. 33053); then added gratuitous insults in the form of remarks about petitioner and

Davis intelligently explained that a number of questions would be required to bring out the full consequences of non-Gaussian distribution, Judge Davidson made the totally irrelevant and distracting remark, "I explained to you that you could not testify". (Tr. 33056).

Regarding the photographic blow-ups of exhibit 0-932 which petitioner had brought into the hearing room for use in cross examination, Judge Davidson charged that they were "more for the benefit of the audience and possibly yourself than it was for any of the other participants." (Tr. 33255).

The foregoing are representative samples of the petty but effective harassment and abuse practiced by Judge Davidson, which

Dr. Davis having had a tape recorder at the hearing, so Dr. Davis should have known what sustaining an objection means; then followed further with elitist remarks about Dr. Davis not being an attorney, and inaccurate statements that Judge Davison had been giving him "as much leeway as I can"; and followed still further with more insult:

JUDGE DAVIDSON:. . . if your best is not good enough to meet the needs, then you should have an attorney asking these questions and not yourself. "
(Tr. 33054).

Then Judge Davidson continued hectoring the cross-examiner, inaccurately charging him with saying the same thing many times, and "Try to explain it to me. I wish you could". Then when Dr.

continued throughout the cross examination by Dr. Davis.

Eventually, Judge Davidson ruled out questioning on Gaussian distribution (Tr. 33065), although much of the subject remained to be covered. This ruling resulted in a severe restriction on the use of exhibit 0-932 as a tool in questioning. Such use was essential in order to hold Dr. Harper to the subject and to get definite answers from him.

Permission was requested to appeal to the Commissioner the refusal to allow use of exhibit 0-932 as a tool in questioning, and that also was denied. (Tr. 33254). Motion to admit exhibit 0-932 into evidence was denied. (Tr. 33521). It was carefully explained to Judge Davidson that petitioner was surprised by the lack of statistical competence shown by the Board, that this could not have been known until Dr. Harper or other member of the Board could be cross-examined on the subject, and that therefore petitioner was entitled to bring on rebuttal witnesses, and to present the Commissioner with adequate scientific facts by which to judge the Board's RDA's on which the FDA Regulations are based.

Judge Davidson took the position that petitioner had had his opportunity to present rebuttal witnesses in the original hearing of 1968-1970, and denied the motion to bring in rebuttal witnesses. (Tr. 33521).

ARGUMENT ON ISSUE OF STATISTICAL METHODOLOGY

It is clear that the adequacy of the RDA's depends heavily on competent statistical treatment of basic nutritional requirements, regardless of whether requirements are derived from consumption data, nutrient levels in apparently healthy people, or experiments on animals or humans. This is shown by the repeated reference to statistics in the Board's reports (P-651, P-1165). Cross examination of Dr. Harper brought out that in every case where the Board has to make an important statistical assumption, which was often because of the paucity of basic data with which they had to work, the Board makes the assumption which will produce the lowest RDA.

All the statistical assumptions made by the Board are unjustified, but the most reprehensible is the third assumption, because it is unstated and violates elementary statistical principles. This assumption is that the risk of each RDA not meeting the needs of the population can be considered to be independent of the risk of all the other RDA's.

In the development of RDA's, it is of course necessary to

begin with one nutrient at a time. But the Board ignores the obvious fact that health requires the regular ingestion of adequate amounts of all essential nutrients at the same time in each person, which must be considered in the statistical calculations which are used in the formulation of the RDA's. Dr. Harper admitted that this factor of multinutrient need is important, that it would raise any RDA, and that the Board ignored it.

The reasons why it is statistically improper to ignore the fact that all forty or more nutrient requirements must be met simultaneously in each person, and to ignore the implications this has for the proper setting of RDA's, may now be explained in more detail.

Even if RDA's were properly determined, each of which would independently meet the needs of all but, say, 2.5% of a population, it does not follow that a population needing some 40 RDA's would be well nourished except for a mere 2.5%. Nowhere do Dr. Harper or the reports of the Board consider the serious statistical effect of taking a 2.5% risk of deficiency for nutrient no. 1, along with a 2.5% risk for nutrient no. 2, along with a 2.5% risk for no. 3, and so on for 40 or more nutrients.

Exhibit 0-932C shows the statistical relationships involving 10, 20, and 40 nutrients, the needs for which are to be met simultaneously in a single person. Assuming a Gaussian distribution, and independence of the variables, it is seen that RDA's based on 2 standard deviations used by the Board

and which individually do not meet the needs of about 2.5% of a population will be insufficient for 20% to 60% of a population when 10 to 40 nutrients are considered. To overcome this problem, the RDA's would have to be raised to about 3 standard deviations above the average.

If the actual distributions are non-Gaussian, the implications become more serious. For example, with the non-Gaussian curve II (0-932D) the RDA's would have to be set about 4 to 5 standard deviations above the average requirement in order simultaneously to meet the needs of 97.5% of the population for 10 to 40 relevant nutrients. If left at 2 standard deviations, these RDA's would exclude from 35% to 80% of the population.

In addition to these indications that the RDA's should be based on 3 to 5 standard deviations above the average, Dr. Harper testified that the standard deviations themselves are poorly known at best, and that many are probably larger than the 15% assumed by the Board. Therefore, where the Board might raise a 10 mg average requirement to an RDA of 13 mg, as illustrated previously, it might more properly raise it to an RDA of 10 mg plus 4 times a standard deviation of 25%, producing an RDA of 20 mg.

In summary of the cross examination of Dr. Harper on the statistical methodology of the RDA's, it appears that the Board, in setting the RDA's as low as it dared, has clothed them with a

spurious statistical respectability.

Until now the Board has not been challenged on its own ground. It is an elite appointed body, remote from the consumer, beholden to the food industry, and closely allied to the FDA. (Another organization well known to have problems of domination by industry). The full extent and significance of the Board's statistical incompetence could not be brought out in the FDA Rehearing, because Judge Davidson improperly restricted crucial lines of inquiry in the cross-examination, including a full and sufficient use of the statistical graphs in exhibit 0-932, as tools in questioning. This use was justified because Dr. Harper did not question their applicability to the discussion, and they were partially used. It is unreasonable to expect that verbal discussion of a mathematical matter, severely restricting the use of actual figures on display, could be satisfactory to the scientists concerned or clear enough for an intelligent decision by the FDA Commissioner.

If petitioner had not been denied cross-examination of the previous Board's representative, Dr. Sebrell, on January 13, 1970, in the original hearing, he would have been able to present rebuttal when the written direct testimonies of his eighteen witnesses were filed on March 6, 1970, and could not now justifiably complain. But petitioner did not have this opportunity. The important issue of statistical competence of the Board appeared for the first time at

the FDA Rehearing. It was, therefore, prejudicial error to deny rebuttal on this issue. 5 U.S.C. para. 556(d) applies to this case and provides for rebuttal. Mr. Krulwich and Mr. Turner, representing Hoffman-LaRoche and the Council On Responsible Nutrition respectively, supported petitioner's motion for rebuttal (Tr. 33501).

There cannot be a parry without a thrust. Petitioner carefully pointed out to Judge Davison (Tr. 33496-50) that he was denied the thrust of revelations from the Board's chairman, Dr. Sebrell, under cross examination*, so he had nothing concerning the Board to parry with his witnesses in the original FDA hearing. Petitioner is not trying to delay the resolution of this matter. At all times, it has been the FDA which has moved at a leisurely pace. See, for example, petitioner's motion and affidavit to disqualify Judge Davidson filed in this Court, mentioned herein on p. 4 and footnote on p.53 .

STATEMENT OF THE CASE ON ISSUE OF THE BOARD IGNORING
ACADEMY'S NUTRIENT REQUIREMENTS FOR ANIMALS

Petitioner and his associate, Dr. Davis, were interested in whether the Board had set the RDA's lower than would be justified from the standpoint of the nutritional requirements of animals. As a tool for use in questioning, they constructed a series of bar graphs (0-931) comparing the Board's RDA's with the nutritional requirements of rats and monkeys established by the Board's parent

* Mr. Krulwich, counsel for Hoffman-LaRoche stated that according to his recollection there was no testimony on the statistical methodology of the RDA's in the original FDA proceeding. (Hearing of 1968-1970). (Tr. 33500-01).

organization, the National Academy of Sciences. These requirements are of the nature of RDA's, since they are obviously intended to cover the range of variation in the animals. The data are contained in the Academy's Handbook No. 10, excerpts from which are exhibits 0-936 and 0-937. The link between the animal and human data consisted of converting the data for each to a common denominator or parameter of daily nutrient dose per 1000 kilocalories of food energy intake. The justification for this conversion is described below.

The Board's 1974 text of RDA's (P-1165) shows substantial dependence on animal data used in formulating the RDA's. According to the Board, this is partly because so little work has been done in this field on man, and partly because it is more feasible to perform thorough and critical experiments on animals which would be unethical to do on man. (P-1165, p. 5). The Board states that "It is possible, by expressing the allowance for each essential nutrient in relation to the allowance for energy, to devise a standard expressed as units per 100 kcal." (P-1165, pp. 19-20).

Taking advantage of the more or less stable ratio of nutrient amount/total calories of food intake (commonly expressed as nutrient/1000 kilocalories, see infra), which tends to hold regardless of species, the Board also extrapolates nutrient requirements across the line between animals and man.

* Deputy Agriculture Secretary John C. White stated last week, "It is true today that we know more about the nutrition requirements of our pets - the poodle I have at home - than my own children." (Food Chemical News, August 1, 1977, p. 73).

For example, in determining protein needs, the Board states that these are quite uniform per kilocalorie of energy utilization among "mammals generally" (P-1165, p. 38), and that the "nutritive value of a protein or food (for human consumption) is most commonly assessed. . . on young rats". (Ibid., p. 46). Other references are made to information from animal experiments about protein needs. (Ibid., pp. 39, 41).

In the case of "both human subjects and animals. . . the required intake of essential fatty acids lies within the range of 1-2 percent of total calories" (Ibid., p. 50). The relationships between the two forms of vitamin A in foods "were derived from studies on the rat and are assumed to hold for man" (Ibid., p. 50), and data on storage of vitamin A in the liver of animals is utilized in planning its RDA for man (Ibid., p. 53). A low intake of vitamin E produces the same increased susceptibility of red blood cells to in vitro hemolysis "in both experimental animals and man." (Ibid., p. 56). The sensitive indicator of deficiency of thiamin known as reduced red blood cell transketolase activity is common to both man and animals (Ibid., p. 66). Maximal transketolase activity in man requires a thiamin intake of 0.6-0.8 mg/1000 kilocalories (Ibid., p. 67).

The Board's calculations of the RDA's of both riboflavin and niacin were made principally on an energy basis, arriving at a figure for riboflavin of "0.6 mg/1000 kcal for people of all ages." (Ibid.,

p. 69), and for niacin of 6.6-8 mg/1000 kcal for all ages (Ibid., pp. 70-71).

The Board notes that "as with animals" the requirement of vitamin B₆ increases on high protein diets, but information on the requirements of human adults, children and adolescents is inadequate. (Ibid., p. 76). As for pantothenic acid, the Board concludes that "Insufficient evidence exists on which to base recommended allowances", although "Dietary deficiency of the vitamin in nonruminant animals results in a broad spectrum of abnormalities", and "marginal deficiencies may well exist in generally malnourished [human] individuals" (Ibid., pp. 79-80). Similarly, the Board recognized that biotin is a vitamin "essential for many animal species, including man", but refused to set an RDA.

FDA overrode the judgment of the Board, and set RDA's for both pantothenic acid and biotin. (41 Fed. Reg. 46172). FDA also set an RDA for copper which the Board had failed to set.

Dr. Harper was asked whether the Board had "used animal data to help you arrive at the RDA's in some cases", and he replied:

DR HARPER: "I don't remember that being in the publication itself [P-1165], but I am sure I have stated it in talks that I have given that you may have at hand" (Tr. 32850-1).

Yet, as cited above, the Board specifically described the use of animal data in setting the requirements for protein, essential

fatty acids, and vitamins A and B₆. Under further cross examination, Dr. Harper admitted that animal data were used in connection with the RDA for vitamin E and folic acid (Tr. 32873), niacin and iron (Tr. 32874), Cu, selenium, manganese, and B₆ (Tr. 32875); and that while they did not set an RDA for biotin, animal data had been considered (Tr. 32876). When he was asked if "estimates have been made on animals of their biotin requirement", the question was not allowed by Judge Davidson:

JUDGE DAVIDSON: "I will have to sustain that, I don't see any relationship between the animal needs and estimates made with respect thereto and what we are talking about here today." (Tr. 32877).

With regard to the extrapolation from animals to man by means of the common denominator of a particular nutrient need per calorie of food energy, Dr. Harper confirmed that the Board used this principle:

Q. . . . it is my understanding in work of the sort that you do that whenever you do make an extrapolation from animal to man with respect to nutritional requirements that one can do it either on a per kilogram of body weight basis or on a per calorie of food energy basis, am I correct on that?

A. . . . Yes. It may depend on the nutrient. (Tr. 32851-52).

Exhibit 0-931 shows nutrient requirements in the form of bar graphs for rats and monkeys derived from data in the National Academy of Sciences' monograph, "Handbook No. 10 - Nutrient

Requirements of Laboratory Animals" (0-936, 0-937); and for humans derived from the Board's RDA's for three ages of man. (P-1165, fold out page). Motion to admit the aforesaid petitioner's exhibits into evidence was made, but erroneously rejected. (Tr. 33521). The data in these two sources, were converted in the graphs of exhibit 0-931 to nutrient requirements per 1000 kilocalories of food energy utilization. The purpose of the graphs was to test whether the Board had properly taken into account the Academy's animal data in setting the RDA's, especially from the standpoint of the criterion of dose per unit of food energy, which appeared to make extrapolation between species, and between ages within species, unusually feasible and productive.

When first faced with the bar graphs (0-931), Dr. Harper totally rejected one of the two propositions demonstrated by it, that the requirement of a given nutrient for different ages of the human species is very much the same on an energy basis:

A. . . . Is it true that for virtually all the nutrients that the nutrient requirement within the human species, that is to say an infant, child and adult, that that nutrient requirement is very much the same for infant, child and adult on an energy basis?

A. . . . No, that is absolutely wrong. (Tr. 32864).

But soon he retreated from this categorical denial. He admitted that "for thiamin I would accept a caloric comparison" (Tr. 32885), that it also held for riboflavin (Tr. 32886-7), and did not

disagree with the bar graph for vitamin E (0-931) showing that the proposition held also for this vitamin (Tr. 32889). He agreed that for at least B₁ (thiamine) and B₂ the requirement is more directly related to energy than any other parameter (Tr. 32888-9).

When his attention was again directed to exhibit 0-931 and asked if he would like to check the authenticity of the calculations, he waived any such doubt aside, stating that he had seen RDA figures calculated in this way "quite close to what you have here", that the Board did at one time, consider including such a Table in the bulletin (P-1165)", but decided it would be too difficult for the dieticians using the bulletin to understand the concept. (Tr. 32892).

In deprecating the energy criterion, Dr. Harper said that the "best basis I could think of" for the correlation of nutrient requirement with either age of species is according to the three quarter power of the body weight. (Tr. 32885-6). But when Dr. Harper was working on the RDA for protein, the nutrient which is his particular specialty (Tr. 33348), he used the energy parameter to make a comparison between the protein requirement for human babies and monkeys. He testified that they showed the same protein requirement per calorie utilization, and that "This was the type of comparison we made." (Tr. 32883).

When Dr. Harper was asked what data were available showing the alleged superiority of the criterion of body weight to the 3/4 power for

correlating requirements for different ages within a species, or between species, he stated that in only a few cases had it been calculated, and he had not seen it tabulated. (Tr. 32886).

The Board's text states:

"It is possible, by expressing the allowance for each essential nutrient in relation to the allowance for energy, to devise a standard expressed as units per 100 kcal." (P-1165, pp. 19-20).

The purported reason the Board's RDA's were nevertheless expressed as amount per body weight, rather than per energy expenditure or per body weight to the $3/4$ power, was "in order to simplify calculation." (P-1165, p. 5).

As a matter of fact, the parameter of body weight to the $3/4$ power runs parallel to the energy parameter, as shown by Dr. Harper's testimony that the "three-quarter power of the body weight . . . is the basis, certainly, for basal metabolic rate." (Tr. 32886). As is well known, the latter is expressed in calories.

Having established that Dr. Harper to a considerable degree accepted the authenticity of the bar graphs in exhibit 0-931, it was intended to probe why the Board had apparently felt justified in ignoring the animal evidence compiled by the Academy, especially since the bar graphs showed in a startling manner that many of the nutrients well known to be highly controversial were the very nutrients for

which the Academy's animal requirements were far greater than the Board's human RDA's.

Dr. Harper had testified as to the Academy's Booklet No. 10 (0-936, 0-937) that "It's a perfectly reliable booklet prepared by competent authorities" (Tr. 32898-99). He agreed that the articles in the Booklet had 250 to 300 references to the scientific literature and that the authors were reputable scientists, two of whom he knew personally (Tr. 32895-6). He personally had a copy, and used it regularly in his work, "for information, for nutritional experiments" (Tr. 32898). But he said it was not suitable for assistance in determining the RDA's because it was only "a summary guide for people who are working with animals", and "does not provide original data" (Tr. 32880). He said "I don't know of a booklet that would give a good summary of comparative animal requirements" (Tr. 32894).

Petitioner attempted to probe Dr. Harper's connection to the authors of Bulletin No. 10, one of whom was the Dr. Hoekstra in line to receive the \$50,000 professorship from General Foods. The purpose of the line of questioning was to find out if Dr. Harper's rejection of Bulletin No. 10 for RDA purposes was sound. At this point Judge Davidson terminated the inquiry. (Tr. 32895-32900).

Petitioner then moved to introduce exhibit 0-931 into evidence, but this was denied. (Tr. 32901). An oral interlocutory appeal was made to the Commissioner, but he upheld Judge Davidson's

ruling against both admission of exhibit 0-931, and pursuit of the line of questioning, on the ground that the "animal standards [in exhibits 0-931, 0-936, 0-937] had not been utilized by the Board." (Tr. 32910-11). *

Motion was made for permission to bring in rebuttal witnesses to testify that the Academy's animal data in its Booklet No. 10 should have been considered by the Board in setting the RDA's (Tr. 33495), but this was denied. (Tr. 33503).

ARGUMENT ON ISSUE OF THE BOARD IGNORING
ACADEMY'S NUTRIENT REQUIREMENTS FOR
ANIMALS

It appears from Dr. Harper's testimony that the Board pays attention to animal data only where this does not conflict with its bias aimed at holding the RDA's down to a level which will not embarrass the reputation of modern processed food, nor exceed the per capita ceiling of nutrients available with that food.

Dr. Harper gave contradictory testimony about the Board's dependence on animals and its use of the energy (calorie) parameter. His attack on the utility of Booklet No. 10 as being only a summary of knowledge was irrational on its face. In order to be useable, scientific knowledge has to be evaluated and distilled by experts from

* Transcript of this oral appeal is in the certified record as FDA item No. 51, filed January 2, 1976.

a vast amount of original data, which is obviously how the nutritional requirements for animals in Booklet No. 10 were determined. The Board's own RDA text was purportedly produced in precisely the same way. Accordingly, a probe of startling discrepancies between the two compilations of recommendations was entirely reasonable.

It was prejudicial error to deny admission into evidence of exhibits 0-931, 0-936, and 0-937; and to deny further questions on the subject. Dr. Harper had substantially authenticated the accuracy and relevance of the bar graphs, and could easily have resolved any doubts by a little study, with the aid of the complete references contained in the tables accompanying the graphs. The sources of all the data were unimpeachable, being from either the Board itself, or its parent, the Academy.

The Board states, and Dr. Harper confirmed, that the energy (calorie) parameter can be used to express nutrient allowances, and that this method is used to make comparisons between animals and man. (P-1165, pp. 19-20, Tr. 32851-52).

Dr. Harper admitted that the Board had even considered using this form for expressing allowances in the Board's 1974 report on RDA's, but said this was rejected because dieticians were so poorly trained that they could not grasp this elementary concept of nutrient density per calorie of food energy. (Tr. 32887).

However, it is more likely that the real reason why the Board did not present nutrient requirements in this fundamental way was that it would dispel much of the obfuscation by which the Board maintains its elite, and also lead to an embarrassing comparison with the more precisely determined animal requirements shown in exhibit 0-931. *

In the field of nutrition, it would be hard to imagine a more arresting red flag than the contrast between animal and human requirements for certain nutrients shown by the bar graphs in exhibit 0-931.

The contrast is most dramatic for the very nutrients about which there is so much controversy. For example, this Court's decision in this same matter (2d. Cir., Case No. 73-2129 et al) took notice of the "particularly wide variations in philosophy concerning the optimal intake of vitamin C" (504 F. 2d. 783), and of the need for women on oral contraceptives for increased doses of vitamin B₆ (504 F. 2d. 791). In another recent and related decision, this Court

* The current Chairman of the Board's RDA Committee, Dr. H. N. Munro of MIT, "reported that the Ninth Edition of the Board's Recommended Dietary Allowances, to be published in late 1978 or early 1979, will probably have some major changes or anticipated innovations including: *** possible expression of allowances per 1,000 calories. Munro indicated that the Committee may hold an open session to solicit advice on problems concerning dietary allowances and their uses." (Food Chemical News, November 22, 1976, p. 38, emphasis supplied).

has substantially relaxed FDA's authority to restrict the non-prescription sale of vitamin A in doses above the RDA (F. 2d.). It is also fairly common knowledge that many people are taking doses of vitamin E for the heart and other conditions, and niacin for psychoses (Tr. 9976-77), all in doses much higher than the RDA.

The bar graphs of exhibit O-931 show that all of the aforesaid controversial nutrients are ones for which the Academy has set much higher requirements for rats and monkeys than its Food and Nutrition Board has set in the form of RDA's for humans. Strikingly, for most of the nutrients about which there has been little or no controversy over the human requirement, e. g. vitamins B₁, B₁₂, D, biotin, and iodine, the animal and human doses judged by the parameter of dose per calorie are remarkably similar. This greatly strengthens the validity of using the criterion of dose per unit of energy, in extrapolating between animals and man.

The FDA's RDA (U. S. RDA) for biotin is a particularly strong example of the principle: when in doubt follow the animal requirement (Tr. 32876). The Board states that the amount humans need is uncertain (P-1165, p. 8), and one finds that the FDA has set the RDA between the rat and monkey requirements. (O-931, p. 2).

If the Board had taken into account the authoritative and detailed animal requirements of Booklet No. 10, this would have called into question the

comparatively low RDA's for nutrients about which there is great controversy. By ignoring any animal data which might raise the RDA's, and by neglecting the most fundamental parameter, dose/energy, by which the nutrient needs of animals and humans can be compared, the Board could favor the food industry and keep most critics of the elite on the outside, uninformed and disarmed.

Perhaps the Board did not notice the "red flag" inherent in the contrast between the two work products of the Academy, one for animals and one for man. That would be nearly as reprehensible, amounting to incompetence.

Petitioner was entitled to probe fully into this matter, to ensure that the Commissioner would be fully informed. Petitioner should also have been allowed to bring in rebuttal witnesses, with respect to whether more weight should have been given by the Board to the Academy's nutritional requirements for animals, and particularly monkeys, and whether the Board's use of statistics was incompetent.

Petitioner carefully explained to Judge Davidson (Tr. 33486-33489) that this Court had noted that the previous examination of Dr. Sebrell had not secured answers to the "harder questions about the basis for the [RDA] figures in scientific fact" (504 F. 2d. 795 , fn. 52, 2d. Cir. 1974), and that the Court's "examination of the record has turned up not a single instance in which the scientific processes

by which the RDA figures were developed were subject to searching examination." (Ibid., p. 798, fn. 62).

Petitioner also explained (Tr. 33495-33500) that he felt entitled to rebuttal in three areas: the Board's statistical methodology, its use of animal requirements in the formulation of the RDA's, and the formulation of the RDA for vitamin C. Judge Davidson's position from the start of the FDA Rehearing was that petitioner had already had his opportunity for rebuttal in the original hearing (Preh. Tr. 63), but on the last day conceded that rebuttal would be in order if "opponents could show some specific surprise." He ruled, however, that such had not been shown. (Tr. 33502-03).

Petitioner, however, had not had an earlier opportunity for rebuttal. The previous representative from the Board, Dr. Sebrell, testified on January 13, 1970; and in due course on March 6, 1970, petitioner filed the written direct testimonies^{*} of 18 witnesses. But having been denied the opportunity cross-examine Dr. Sebrell, petitioner had no way of knowing, as this Court has pointed out, the details of methodology employed by the Board. This knowledge was essential for effective rebuttal, and if the original hearing had been fairly conducted, would have been available to petitioner.

* FDA's conception of rapid progress in its 1968-70 hearing was for its witnesses to give oral testimony for as long as 49 days on the stand (Weissenberg), then change the hearing rules and restrict the opponents to quick written direct testimony. (Order, Feb. 4, 1969).

It was reversible error when Judge Davidson not only restricted the probe of the Board's failure to consider the Academy's nutritional requirements for animals, but also denied the opportunity to present rebuttal witnesses on this and the statistical methodology of the Board. Without such rebuttal there cannot be a full and true disclosure of the facts, by which it may be judged whether the levels of the RDA's set by the Board are scientifically sound.

The total indifference of Dr. Harper and the Board to the animal data compiled by the Academy strengthens petitioner's position that the Board has been so blinded by conflict of interest that it could not develop or retain an objective scientific interest in the optimum nutritional requirements of man. The Board seems not to have been able, or had the open-minded courage, to search out nutritional truth, and to put aside those commercial and political considerations which ought to be faced as separate issues. Instead, it has built a monopoly of questionable standards - narrow, confused and self-serving.

STATEMENT OF THE CASE ON ISSUE OF SUFFICIENCY REGARDING CERTAIN RDA'S

Dr. Harper admitted that new and more sensitive criteria for satisfaction of the nutrient requirements in man have been developed, and that these

may not have been utilized either in the 1968 or 1974 RDA's issued by the Board. (Tr. 33362-63, 33397).

The criterion for adequate nutrition for vitamin A used by the Food and Nutrition Board was the absence of night blindness. (Tr. 33425-33426). Dr. Harper agreed that both rats and humans need more vitamin A for reproduction and lactation than they need for the prevention of night blindness. He agreed that the rat needs 19 times more, and that the human RDA is set at only 3 times more (Tr. 33432-33, 33436-37).

He did not know whether vitamin A content of the liver is a more sensitive criterion than night blindness of deficiency (Tr. 33426). He uses the textbook of Goodhart and Shils in his classroom (Tr. 32601-02), but did not know that according to this text the content of vitamin A in the liver can vary by a factor of more than seven fold. (Tr. 33429). He was aware that Canadian authorities have been concerned about inadequate levels of vitamin A in the livers of Canadians. (Tr. 33439).

As for vitamin D, petitioner has no quarrel with the level of its RDA, because it is within the order of magnitude of the monkey dose on a per calorie of energy basis (0-931). But petitioner raised the question of whether the Board had been negligent in making no distinction between the two common forms of vitamin D.

The form universally added to milk and mostly used in food

supplements is the artificially irradiated ergosterol known as D_2 . Whereas, the natural form synthesized in the skin by sunlight and found in animal products is D_3 . Dr. Harper believed both were equally active in man (Tr. 33464-65), and was surprised to learn from the National Academy of Science publication, booklet No. 10 (0-936), that some monkeys suffer demineralization of bone on the artificial D_2 . (Tr. 33468, 33472).

The question raised was whether the common demineralization of bones seen in some people (especially the elderly) could be due as in some monkeys to a relative inability for man to utilize the artificial vitamin D_2 . Dr. Harper said he preferred human evidence, (Tr. 33466-69).

Dr. Harper testified that the question of relative effectiveness of the two forms of vitamin D actually was discussed with the committee member of the Board in charge of this vitamin, Dr. Alfin-Slater. They concluded that they did not have information to decide whether there may be people who do not use the two forms equally well, and decided to make no distinction between them in the RDA. (Tr. 33474). According to the Board's text, both forms seem equally effective, but the work on which this is based is 40 years old (P-1165, p. 55).

Dr. Harper stated with reference to vitamin D:

"it is generally understood with most nutrients that when allowances and recommendations are set the recommendation is for the naturally occurring form." (Tr. 33472).

This would certainly come as a surprise to a great many people ingesting artificial vitamin D₂ in milk and other foods.

With regard to vitamin E, Dr. Harper testified that the RDA for vitamin E is fundamentally based on current intakes. (Tr. 32937-78). The 1968 RDA depended extensively on the work of Dr. Horwitt (P-651, p. 28, ref. 8), yet the Board's 1974 RDA was cut in half against the advice of Dr. Horwitt. (Tr. 33365). Part of the reason for the reduction was based on the Elgin study (Tr. 33359, 33362*), but the technique used at that time to detect E deficiency is not as sensitive as a more recent Israeli technique which was not used. (Tr. 33362-3).

There is also another new and sensitive technique involving the detection of Heinz bodies in blood on challenge with a combination of ozone and unsaturated fats, but the Board did not consider this technique either. (Tr. 33397).

With respect to vitamin C, the Board depends heavily upon an analysis of the pool of vitamin C in the body. (P-1165, p. 64). But under cross-examination Dr. Harper stated that relatively little is known about the different types of pools of vitamin C. (Tr. 33374), and that the definition of body pool "depends on who is using the term". (Tr. 32614).

* There are two transcript pages numbered 33362. Reference here is to the second one.

Since the Board's 1974 RDA's purport to represent the most advanced thinking and methodology for determining RDA's we were prepared to cross examine Dr. Harper on the method used for the RDA of vitamin C described in P-1165, p. 64. However, Judge Davidson would not allow any questions on this methodology (Tr. 33409-13), and we had to abandon our cross examination on vitamin C.

ARGUMENT ON ISSUE OF SUFFICIENCY REGARDING CERTAIN RDA'S

As a guide to the argument in this section, attention is directed to the bar graphs in exhibit 0-931, which highlight those nutrients for which the recommended daily dose is substantially higher for the monkey and rat than it is for man.

It is submitted that Dr. Harper and the Board have not carefully evaluated the scientific data on vitamin A, particularly from the standpoints of liver stores and of the much larger daily allowance on an energy basis recommended by the National Academy of Sciences for animals (0-931, 0-936).

Dr. Harper and the Board have treated the matter of vitamin D_2 v. D_3 in a very cavalier and negligent fashion, giving no warning to the public of the hazard of D_2 for some primates, particularly in view of the widespread occurrence of human osteoporosis (demineralization of bone).

It was unscientific and reprehensible for the Board to set RDA values for vitamin E primarily on the status quo of the E content of food, while ignoring new and more sensitive criteria of E deficiency. To cut the Board's RDA in half from 1968 to 1974 under these conditions, and to reject the most recent advice of the very expert the Board was still depending on (Dr. Horwitt and his Elgin Studies (Tr. 33359, 33362). was even more deplorable. It was prejudicial error to deny examination of the methodology used for the 1974 RDA of vitamin C. The public is entitled to know not merely old methodological history, but the latest methodology. It was also inconsistent, for we had already been allowed to discuss some of the 1974 RDA's, for example the reduction to one half of the 1968 RDA for vitamin E.

Since this Court, in its earlier decision on the regulations had expressed particular concern regarding limitations (504 F. 2d. 785, 6) on the optimal (Ibid. , 783) dose of vitamin C, the denial was all the more in violation of the purpose of the remand.

When one is attempting to explore methodology in science, it is preposterous to shut out the use of numbers involved in a methodology one wishes to explore. Judge Davidson enforced here the same erroneous prohibition ^{(as} in the area of statistics.

It was surely not the intent of this Court's mandate to have such severe restrictions applied to a scientific examination of the methodology used by the Board to set the RDA's.

STATEMENT OF THE CASE ON ISSUE OF
INEQUITABLE AND IMPROPER PROCEDURAL RULINGS

Throughout the prehearing conference and FDA Rehearing, petitioner routinely behaved in a courteous and restrained manner toward Judge Davidson. Nevertheless, Administrative Law Judge Davidson at the very start instituted a policy of unfairly harassing petitioner, even (Preh. Tr. 3, 4, 17, 27). He set up a ground rule which severely discriminated against petitioner, compared to advantages the FDA had had in all its cross examinations. This rule consisted of doubling the number of hours per day which petitioner would be required to cross examine, in comparison with the hours required of FDA in all its cross examinations. (See Tr. 32416-20 and petition and motion for disqualification filed in this Court, November 5, 8, 1975, Case No. 73-2129 et al.) The long hours would impair the effectiveness even of a lawyer, especially in such a complex scientific matter as this. If petitioner had been given as much interim preparation and rest time as that enjoyed by FDA lawyers in all their cross examinations, he could have coped much better with Judge Davidson's persistent efforts to hamstring him with the legal rules of cross examination. * Petitioner fully recognizes the necessity of such rules; but in this fact-finding scientific hearing, it would have been reasonable for Judge

* (Tr. 32622, 32835-37).

Davidson to have explained the rules, and to have assisted petitioner in their observance. Instead, the following was typical of his attitude:

"Don't ask me how to do it because you're not paying me a fee to be your attorney." (Preh. Tr. 41).

Judge Davidson made sure petitioner's interim preparation and rest time were cut to the bone by requiring all parties to be constantly in attendance under penalty of forfeiting their right to cross-examine (Tr. 32554, 32632, 32691, 32837), whereas petitioner had no interest in areas covered by other cross examination. No such rule was enforced against the FDA in the original hearing.

Petitioner was also severely handicapped by lack of a next-day transcript, which Judge Davidson refused to order (Preh. Tr. 20-23, 32643-49), resulting in a seven-day transcript (Tr. 32633). FDA for all its cross-examinations had the ^{(great} benefit of a next-day transcript, and even a same-day transcript when desired. (Tr. 4988, 12850, 13103).

Judge Davidson repeatedly interfered even with the marking of petitioner's exhibits (Tr. 32598, 32601, 32863-64, 33504, 33508-9, 33514-16, 33523). At one point, it required five pages of colloquy for petitioner to get his crucial exhibit 0-931 marked for identification. (Tr. 32854-59). Such marking was, of course, imperative for taking an appeal.

At the end of the Rehearing, on a Monday's "finishing up day" after Dr. Harper had been excused the previous Friday, petitioner's reasonable request for information as to whether the admission of three exhibits had been ruled on was met with the following characteristic outburst:

JUDGE DAVIDSON: ...So, exhibits 0-934 through 0-962 are not received in evidence and the Reporter will mark them so.

DR. ROBINSON: What is Your Honor's disposal of 0-931 through 0-933?

JUDGE DAVIDSON: I am sorry, Dr. Robinson. I am tired of having you delay these Proceedings by continually asking things that have already been taken care of. Now, if you don't find it in the transcript, then I assume you go complain to the Court that I am a bad boy, but if I have to rule on those again, I am sorry, I am just not going to.

DR. ROBINSON: No, Your Honor, without the transcript I don't know what you did on them.

JUDGE DAVIDSON: I am sorry about that.

DR. ROBINSON: And that is all I was asking. I am not asking for these --

JUDGE DAVIDSON: Please sit down, Dr. Robinson. You are out of order. (Tr. 33521-22).

Relying on Judge Davidson's assurance that further motions would be in order after the close of the oral hearing (Tr. 33491), if review of the eventually available transcript showed reason for such a motion, petitioner did not move until December 12, 1975, to request Judge Davidson's permission to appeal his denial of rebuttal witnesses to the Commissioner. But Judge Davidson persistently refused to act

on the aforesaid motion of December 12, 1976, even though he was acting on motions of other parties, and forced petitioner to go through FDA legal counsel in order to secure such action. (See petitioner's motion and memorandum for disqualification of Judge Davidson dated March 17, 1976, and filed in FDA proceeding).

ARGUMENT ON ISSUE OF INEQUITABLE
AND IMPROPER RULINGS

The position of the presiding officer at FDA hearings, formerly a hearing Examiner and now termed the Administrative Law Judge, is obviously an extremely sensitive and important one from the standpoint of enforcing legitimate FDA policy. But the leadership of FDA seems to want only the sort of Presiding Officers who will carry on FDA's policy of denying due process in the agency's hearings, exemplified by the conduct of Examiner Harris in the original FDA hearing on vitamin supplements as to which this Court has noted:

"tortured reasoning *** his ill chosen wish *** brinkmanship *** egregious error *** blatantly erroneous restriction" (504 F. 2d 795, 796, 798, 799).

Judge Davidson has continued and enlarged that same pattern of abuse. His attitude was that the previous hearing had been a "three ring circus" (Preh. Tr. 6), and that petitioner was not the victim but somehow the perpetrator of that abuse. Petitioner was generally so staggered by the unbridled hostility and jumbled verbosity with which Judge Davidson repeatedly took advantage of petitioner's legal failings (unfortunately increased by the five-year hiatus of legal inactivity,

since the original hearing), that it is a wonder he and his associate, Dr. Davis, made any progress in the scientific side of the cross-examination.

Judge Davidson's repeated refusals to act on petitioner's motion to appeal the denial of the rebuttal witnesses, culminated in egregious ex parte communications and violation of separation of powers by Judge Davidson, well indicating the true subservience of the Presiding Officers to FDA-power.*

Cross examination by petitioner and his associate, Dr. Davis, took only the equivalent of three working days (638 pages of transcript), in which time they had to try to accomplish a "searching examination" of the scientific bases of the RDA's mandated by this Court,^{(which} as this Court has observed (504 F. 2d.798), was never even attempted in the original hearing lasting 242 days and producing 32,405 pages of daily transcript. Therefore, petitioner was especially entitled to fair and considerate treatment in a matter of great importance to the American public. The failure on the part of Judge Davidson to provide such treatment and otherwise follow this Court's mandate prevented petitioner from bringing out in adequate detail the short-

* FDA two months earlier had taken the strongest possible stand against such ex parte communications. (40 Fed. Reg. 40691-92. See also petitioner's motion and memorandum to disqualify Judge Davidson, filed in the FDA proceeding March 17, 1976, p. 10).

FDA Commissioner Alexander M. Schmidt, in a speech on June 2, 1975, quoted a former Prime Minister of New Zealand that "While it is important that justice be done, it is of equal importance that justice seem to be done."

comings of the RDA's. Therefore, those parts of the Commissioner's order setting the levels of the U. S. RDA's should be set aside.

ARGUMENT ON ISSUE WHETHER RELIEF PRAYED
FOR IS APPROPRIATE

Section 701(f)(3) of the FDA Act, 21 U. S. C. 371(f)(1) provides:

"(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. ***"

It is contended that the numerous prejudicial errors committed during the course of the FDA Rehearing require that Parts 105.3(b)(1) and 105.85(d)(1) (42 Fed. Reg. 14328, 14332), formerly Parts 125.1(b)(1) and 80.1(d)(1) (42 Fed. Reg. 20292 and 41 Fed. Reg. 46172, 46175) of the FDA Regulations, in the order issued by the Commissioner pursuant to said rehearing, must be permanently set aside.

The cases holding that orders based on hearings of this type must be set aside by a court of law where the hearings were conducted in such a way as to deny to the participants procedural due process are numerous and seemingly beyond dispute.

SUMMARY

It seems clear that the record of these hearings, burdened as it is with unbelievable masses of scientific and pseudo-scientific

material, is nevertheless devoid of adequate proof that the pegging of the RDA's at their presently proposed levels is supported by the kind of legally sufficient evidence which its importance demands. Petitioner's insistence upon what might be considered a restrictive interpretation of the regulatory powers of the FDA stems from his realization that the act of fixing the RDA's is so profoundly significant that it could well influence the dietary habits of hundreds of millions of Americans, for good or for ill, for generations yet to come.

The purpose of these extended hearings, if they served any purpose at all in justification for the years of time which they consumed, was to establish a record, with the clarity of the noonday sun, that this rather drastic step taken by FDA was solidly supported by adequate scientific evidence. It must be conceded that the conclusions of a federal agency, drawn from the evidence presented in open hearing, are clothed with presumptions of regularity; and that the function of an appellate court, in such cases, is but to review the record to determine whether there is substantial evidence to support the administrative conclusions. Nevertheless, the importance of this case demands that the rule be strictly observed, and that the substantiality of the evidence be clearly established. This, it has not been.

It is regrettable that FDA showed such reluctance to be

forthcoming as to the actual scientific evidence in support of the proposed levels of the RDA's. Where the circumstances called for fresh air and sunshine, FDA's strategy seems to have been to keep as many things in the dark as possible, and to make disclosures only under protest. These are the tactics of opponents in an adversary proceeding. They hardly befit an administrative agency who has been asked, in good faith, and who is required by law, scientifically to justify a proposed measure which can have such profound nutritional consequences to so many people. It is incredible, as the Court has already pointed out in 504 F. 2d. 796-7, that FDA should have made this Rehearing necessary in the first place. This necessity resulted from its reluctance to tell its story, candidly, openly, and convincingly. At the Rehearing, unfortunately, one senses the same reluctance. There was no disposition on the FDA's part to "go the extra mile" in furnishing information which, if the FDA's thesis is correct, they should have been quite willing to pour into the record.

FDA's procedural strategy seems to have been to fight a defensive fight, giving no more information than was necessary, and defending the procedures used, to establish the RDA's, when under attack. One searches the record in vain for a clear and all-inclusive statement of what those procedures were. One can read the 33,529 pages of the transcript of the two hearings from front to back, and

still not know, for a certainty, whether acceptable scientific proof exists to justify the levels of the proposed RDA's.

There is evidence that FDA relied on certain doctors and scientists to support such-and-such a finding. But a careful review of the entire record of both hearings shows that only in a few cases did the FDA succeed in getting evidence into the record to support the level of its proposed RDA's, and in no case was the evidence substantial.

In one of those cases, that of Dr. Horwitt's contribution in connection with vitamin E, the evidence appeared, not in the record, but in the Board's 1968 report. (P-651, p. 28). The record, moreover, clearly shows that a cloud of uncertainty was subsequently cast over even Dr. Horwitt's findings, when the Board forsook them against Dr. Horwitt's advice and cut the RDA in half (Tr. 33365) to fit what was then considered to be available in "average diets". (P-1165, p. 59). Even assuming that the 1968 Horwitt findings remained valid, the legitimate question may be asked: why did not the FDA see fit to insert in the record the same kind of evidence in support of the other 16 vitamins and minerals whose RDA's at this stage of the hearing, have little or nothing in the record to support them?

There is much evidence, and argumentation, on what proper statistical methodology was to be used; and the proper value to be placed on animal requirements; on whether "optimum" or "adequate"

should be used as a yardstick; or on whether the absence of night blindness is evidence of vitamin A deficiency. These are excellent points, and, by themselves, tend to support petitioner's thesis. But important as they are, they are ancillary to the dominant question: whether there is substantial evidence to support the RDA's. Petitioner believes there is not.

There is but little evidence on what positive clinical or laboratory testing was actually done to reach the conclusions referred to; or, if such testing was deemed unnecessary, then what alternative methods were adopted, how they were implemented, and what results were forthcoming.

It is for this reason that sections 105.3 (b)(1) and 105.85 (d) (1) of the said regulations should be stayed until such time as a record may be supplied which establishes an adequate scientific basis for such action to be taken.

CONCLUSION

For the above reasons, petitioner respectfully prays that the orders of the FDA dated October 19, 1976, and April 19, 1977, adopting certain levels of the U. S. RDA's, be permanently set aside, as aforesaid.

Dated: August 2, 1977

Miles H. Robinson

Miles H. Robinson, M. D.
Petitioner pro se, No. 77-4104

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Original

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATIONAL NUTRITIONAL FOODS	:	
ASSOCIATION AND SOLGAR	:	
COMPANY, INC., et al.,	:	
	:	
Petitioners,	:	
	:	
v.	:	Nos. 77-4097 77-4104
	:	
FOOD AND DRUG ADMINISTRATION,	:	
UNITED STATES DEPARTMENT	:	
OF HEALTH, EDUCATION, AND	:	
WELFARE, et al.,	:	
	:	
Respondents,	:	

CERTIFICATE OF SERVICE

I hereby certify that copies of the Brief of Petitioner, Miles H. Robinson, M. D. (No. 77-4104), have, this date, been served upon National Nutritional Foods Association and Solgar Company, Inc., and Respondents by first class mail, as follows:

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|---|--|

Attorneys for Respondents (separate service on Mr. McConachie and Mr. McNamara, with 4 copies of briefs to each).

2. No. 77-4097 National Nutritional Foods Association and Solgar Company, Inc. v. Food and Drug Administration, United States Department of Health, Education and Welfare.

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